April 29, 2013

pSivida Reports ILUVIEN® Available in UK

Simple Patient Access Scheme Submitted to NICE for Rapid Review

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV; ASX:PVA), a specialty pharmaceutical company that is a leader in the development of sustained release ophthalmic drug treatments, today announced ILUVIEN® , the first sustained release pharmaceutical product for the treatment of chronic diabetic macular edema (DME), is now available in the UK for treatment of private pay and privately insured patients, as reported by its licensee, Alimera Sciences.

Alimera also reported that it has recently submitted a simple Patient Access Scheme (PAS) to the United Kingdom's National Institute for Health and Care Excellence (NICE) for consideration of the guidance under rapid review. The NICE Appraisal Committee will assess the likely impact of the ILUVIEN PAS and determine whether an update to NICE's previously issued final guidance is warranted, according to Alimera. If the PAS is accepted by NICE, Alimera further reported that ILUVIEN would be funded for chronic DME patients in England and Wales through the National Health Service (NHS). Alimera reported that the NICE Appraisal Committee is scheduled to meet on May 15, 2013 to discuss the ILUVIEN PAS submission with an expected 30-day review period to follow.

"We are pleased that ILUVIEN is now available in the UK," said Dr. Paul Ashton, pSivida president and CEO. "This marks the first availability of a sustained release therapy for patients who suffer from DME and who have not responded to conventional therapies. We believe it provides a welcome additional treatment option for retinal specialists in the UK treating private pay and privately insured patients. We are hopeful that the Patient Access Scheme will be approved and make ILUVIEN available to a larger group of chronic DME patients who are considered insufficiently responsive to available therapies."

ILUVIEN (190 micrograms intravitreal implant in applicator) is a sustained release intravitreal implant used to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Each ILUVIEN implant provides a therapeutic effect of up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FAc). ILUVIEN is injected in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. The applicator employs a 25-gauge needle, which allows for a self-sealing wound. To date, ILUVIEN has been granted national licenses for commercialization by six countries, Austria, the United Kingdom, Portugal, France, Spain and Germany. The national phase in Italy is currently ongoing. ILUVIEN has not been approved by the United States Food and Drug Administration.

pSivida has developed three of the four sustained release devices for retinal diseases that have been approved in either the US or Europe, the most recent being ILUVIEN. Independently, pSivida is developing an injectable, sustained release product to treat uveitis affecting the back of the eye (posterior uveitis) and an injectable, bioerodible product to treat glaucoma and ocular hypertension in collaboration with Pfizer.

About pSivida Corp.

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™. The injectable, sustained release micro insert ILUVIEN® for the treatment of chronic Diabetic Macula Edema (DME), licensed to Alimera Sciences, Inc., has received marketing authorization in Austria, France, Germany, Portugal, the U.K. and Spain and is awaiting authorization in Italy. ILUVIEN® for DME has not been approved in the US. pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis with the same micro-insert as ILUVIEN® for DME. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension. pSivida's FDA-approved product Retisert® is an implant that provides long-term, sustained drug delivery to treat posterior uveitis, a chronic disease of the retina.

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uncertainties with respect to: the FDA's acceptance of Alimera's resubmission of its NDA for ILUVIEN® for DME and Alimera's ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN® for DME in the U.S.; the timing of the commercial launch in Germany and the UK, any effect of the PAS on the NICE final guidance, Alimera's ability to finance, achieve additional marketing approvals, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN® for DME in the EU; financing and success of Phase III posterior uveitis trials including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; development of products using Tethadur and BioSilicon; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; possible influence by Pfizer; absence of dividends; and other factors described in our filings with the SEC. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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